IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen B. Elliott
Serial No. 10/784,266
Filed: 02/24/2004
For: **SYSTEM AND METHOD FOR SYNCHRONIZING THE HEART RATE VARIABILITY CYCLE WITH THE BREATHING CYCLE**

Examiner: Mark Bockelman
Art Unit: 3766

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Commissioner for Patents
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Sir:

RESPONSE TO THE FINAL OFFICE ACTION MAILED OCTOBER 18, 2007

In response to the final Office Action mailed October 18, 2007, Applicant offers the following amendments and remarks. If any fees are required in association with this response, the Director is hereby authorized to charge them to Deposit Account 50-1732, and consider this a petition therefor.

In the Claims:

1-20. (Cancelled).

21. (Currently Amended) [[A]] An instructive method for achieving coherence of a heart rate variability for a human, the instructive method comprising:

providing a target respiratory rate, which is not derived from biological feedback from the human during the entire instructive method; and

instructing the human to ~~breath~~ breathe at the target respiratory rate without use of any biological feedback from the human during the entire instructive method in an effort to achieve coherence of heart rate variability by synchronizing a heart rate variability cycle and a breathing cycle corresponding to the target respiratory rate.

22. (Previously Presented) The method of claim 21 wherein the target respiratory rate is around about 0.085 Hertz.

23. (Currently Amended) The method of claim 22 wherein the target respiratory rate is centered at around about 0.085 Hertz and wherein the method further comprises ~~receiving an adjustment input setting from the human and~~ adjusting the target respiratory rate based on ~~the~~ an adjustment input setting.

24. (Previously Presented) The method of claim 23 wherein the adjustment input setting includes adjustment frequencies arranged in a positive direction and a negative direction relative to around about 0.085 Hertz.

25. (Previously Presented) The method of claim 24 wherein the adjustment frequencies arranged in a positive direction and a negative direction relative to around about 0.085 Hertz are bounded within a range of 0.070 Hertz to 0.100 Hertz.

26. (Previously Presented) The method of claim 24 wherein the adjustment frequencies arranged in a positive direction and a negative direction relative to around about 0.085 Hertz are bounded within a range of 0.060 Hertz to 0.170 Hertz.

27. (Currently Amended) The method of claim 21 comprising receiving a sensory input selection from the human to identify the sensory type for instructing the human to breathe at the target respiratory rate, wherein the sensory input selection identifies at least one of a plurality of sensory output types.

28. (Previously Presented) The method of claim 27 wherein the plurality of sensory output types includes at least one of an audible output, a visual output, and a tactile output.

29. (Previously Presented) The method of claim 28 comprising generating the identified at least one of the plurality of sensory output types based upon sensory input selection.

30. (Currently Amended) The method of claim 29 wherein instructing the human to ~~breath~~ breathe at the target respiratory rate without use of any biological feedback from the human during the entire instructive method in an effort to achieve coherence of heart rate variability further comprises instructing the human to synchronize inhalation with a positive-going aspect of the at least one of the plurality of sensory output types and to synchronize exhalation with a negative-going aspect of the at least of one of the plurality of sensory output types.

31. (Currently Amended) The method of claim 29 wherein instructing the human to ~~breath~~ breathe at the target respiratory rate without use of any biological feedback from the human during the entire instructive method in an effort to achieve coherence of heart rate variability further comprises instructing the human to synchronize a peak positive heart rate with a positive peak of at least one of the plurality of sensory output types and to synchronize a peak negative heart rate with a negative peak of at least one of the plurality of sensory output types.

32. (Previously Presented) The method of claim 21 wherein the target respiratory rate for achieving coherence of heart rate variability varies depending upon at least one of age and personal comfort.

33. (Previously Presented) The method of claim 21 wherein the target respiratory rate for achieving coherence of heart rate variability varies depending upon at least one of age, body inclination, and personal comfort.

34. (Withdrawn) A system for achieving coherence of a heart rate variability for a human, the system comprising:

a plurality of sensory output devices adapted to provide a plurality of sensory outputs; and

a controller adapted to control the plurality of sensory output devices to provide a target respiratory rate, which is not derived from biological feedback from the human, and to instruct the human to breath at the target respiratory rate in an effort to achieve coherence of heart rate variability by synchronizing a heart rate variability cycle and a breathing cycle corresponding to the target respiratory rate.

35. (Withdrawn) The system of claim 34 wherein, in being adapted to control the plurality of sensory output devices to provide a target respiratory rate, the controller is adapted to provide the target respiratory rate at around about 0.085 Hertz.

36. (Withdrawn) The system of claim 35 comprising a setting selector adapted to provide an adjustment input setting to the controller when adjusted by the human and wherein, in being adapted to control the plurality of sensory output devices to provide a target respiratory rate, the controller is adapted to provide the target respiratory rate at around about 0.085 Hertz, to receive the adjustment input setting from the setting selector, and to adjust the target respiratory rate based on the adjustment input setting.

37. (Withdrawn) The system of claim 36 wherein the setting selector is adapted to provide the adjustment input setting representing adjustment frequencies arranged in a positive direction and a negative direction relative to around about 0.085 Hertz.

38. (Withdrawn) The system of claim 36 wherein the setting selector is adapted to provide the adjustment input setting representing adjustment frequencies arranged in a positive direction and a negative direction relative to around about 0.085 Hertz bounded within a range of 0.070 Hertz to 0.100 Hertz.

39. (Withdrawn) The system of claim 36 wherein the setting selector is adapted to provide the adjustment input setting representing adjustment frequencies arranged in a positive direction and a negative direction relative to around about 0.085 Hertz bounded within a range of 0.060 Hertz to 0.170 Hertz.

40. (Withdrawn) The system of claim 34 comprising a setting selector adapted to provide a sensory input selection to the controller when adjusted by the human and wherein the controller is adapted to receive the sensory input selection, wherein the sensory input selection identifies at least one of the plurality of sensory outputs.

41. (Withdrawn) The system of claim 40 wherein the plurality of sensory output devices includes an audio output device adapted to provide an audio output, a visual output device adapted to provide a visual output, and a tactile output device adapted to provide a tactile output, and wherein the plurality of sensory outputs includes the audio output, the visual output, and the tactile output.

42. (Withdrawn) The system of claim 41 wherein the controller, in being adapted to control the plurality of sensory output devices to provide a target respiratory rate, the controller is further adapted to drive at least one of the audio output device to produce the audio output at the target respiratory rate, the visual output device to produce the visual output at the target respiratory rate, and the tactile output device to produce the tactile output at the target respiratory rate based upon the sensory input selection.

43. (Withdrawn) The system of claim 42 wherein, in being adapted to instruct the human to breath at the target respiratory rate in an effort to achieve coherence of heart rate variability, the controller is further adapted to instruct the human to synchronize inhalation with a positive-going aspect of the at least one of the audio output, the visual output, and the tactile output and to synchronize exhalation with a negative-going aspect of the output of the at least one of the audio output, the visual output, and the tactile output.

44. (Withdrawn) The system of claim 42 wherein, in being adapted to instruct the human to breath at the target respiratory rate in an effort to achieve coherence of heart rate variability, the controller is further adapted to instruct the human to synchronize a peak positive heart rate with a positive peak of the at least one of the audio output, the visual output, and the tactile output and to synchronize a peak negative heart rate with a negative peak of the at least one of the audio output, the visual output, and the tactile output.

45. (Withdrawn) The system of claim 34 wherein, in being adapted to control the plurality of sensory output devices to provide a target respiratory rate, the controller is adapted to vary the target respiratory rate depending upon at least one of age and personal comfort.

46. (Withdrawn) The system of claim 34 wherein, in being adapted to control the plurality of sensory output devices to provide a target respiratory rate, the controller is adapted to vary the target respiratory rate depending upon at least one of age, body inclination, and personal comfort.

REMARKS

Applicant has carefully reviewed the final Office Action mailed October 18, 2007 and offers the following remarks to accompany the above amendments. Applicant respectfully traverses the Patent Office's rejections in accordance with the explanations provided below.

Status of Claims

Claims 21-33 remain pending. Applicant has amended claims 21, 27, 30 and 31. Claims 1-20 were previously cancelled. Claims 34-46 remain withdrawn.

Rejection of Claims 23-26 under 35 U.S.C. § 112, ¶ 2

Claims 23-26 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has amended claim 23 to address this rejection and thus this rejection is now moot.

Rejection of Claims 21-26, 32, and 33 under 35 U.S.C. § 102(e) - Stabler et al.

Claims 21-26, 32, and 33 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,836,681 B2 to Stabler et al. (hereinafter "Stabler"). Applicant has amended independent claim 21 to clarify the present invention and to address the rejection under Stabler.

Applicant has amended independent claim 21 to provide that both the target respiratory rate provided and the instructing of the human to breathe at the provided target respiratory rate are done without use of any biological feedback from the human. No biological feedback is used during the entire instructive method. The Patent Office argues that Stabler's initially providing a target breathing cycle of 6 breathes per minute previously read on the claims, although Stabler uses biological feedback thereafter to instruct the patient. (See Office Action mailed 10/18/2007, p. 2). The Applicant has amended the claims to clarify that its claimed invention does not involve any biological feedback during the entire instructive method, whether it be initially or later during the method. Thus, Stabler cannot anticipate or render the claims obvious.

To recap, the claimed invention relates to an instructive method and system for allowing a human subject to consciously control and achieve synchronization of heart beat rate variability (HRV) with breathing cycle without biological feedback. Synchronization facilitates achieving

coherence. The instructive method and system involves providing a target respiratory rate to the human. The human is then instructed to breathe at the target respiratory rate in an effort to synchronize their HRV and breathing cycle corresponding to the target respiratory rate. The target respiratory rate is not derived from biological feedback from the human during the entire instructive method. This is because the Applicant recognized and discovered that a target respiratory rate can be provided to instruct a human on breathing to achieve coherence without feedback of HRV or other biological feedback. The breathing cycle influences the HRV cycle in such a way that the HRV cycle will synchronize with the breathing cycle. This synchronization may occur optimally if the target respiratory rate (i.e. target breathing cycle) is close or equal to the natural center frequency of the HRV cycle, this center frequency being determined by the applicant to be approximately .085Hz.

In contrast to the claimed invention, Stabler involves two types of feedback. The first type of feedback is that Stabler receives sensory feedback from the human regarding their heart beat rate and their breathing cycle (col. 2, ll. 21-28). As the patient thereafter breathes, Stabler displays the patient's HRV and breathing cycle to the patient on a display as a second type of feedback. (See Stabler, col. 2, ll. 35-40, and ll. 41-44 where it includes "teaching the person how to breathe to reach the desired range of HRV and verify that the person reached the desired range of HRV by viewing the display." (emphasis added)). Thus, Stabler's instructive method to the patient is based on biological feedback. Stabler is showing the patient whether their breathing cycle aligns with their heart beat rate cycle based on the breathing and heart beat rate monitoring (i.e. feedback) from the patient.

Stabler further emphasizes its feedback nature at column 4, lines 9 through 18. In this section, Stabler indicates that "coaching with valid real-time feedback for us and the client is extremely effective." (emphasis added) The Patent Office points to column 3, lines 25 through 35 of Stabler to support its position. This is a breathing instruction step. However, as part of this same step at column 3, lines 49 through 51, Stabler provides that a tension strap is provided around the human as a feedback sensing device. A graph of heart rate and amplitude of breathing is displayed to the patient to indicate to the patient whether the HRV and breathing cycles are synchronized in a feedback fashion. Further, when this section is read in context with other parts of Stabler discussed in the preceding paragraphs, including the Summary of the

Invention, which is of particular importance when determining what is taught, it is clear that Stabler is a feedback system.

Thus in summary, Stabler may arguably initially provide a target respiratory rate not based on biological feedback. However, once the patient is breathing and online, Stabler provides a target heart rate to the patient to control breathing based on biological feedback from the patient, namely their breathing and heart beat rate cycles. The claimed invention excludes biological feedback to provide the target respiratory rate or instructions to the patient for the entire instructive method. Thus, Stabler cannot anticipate the claimed invention, and this rejection must be withdrawn.

Rejection of Claims 27-31 under 35 U.S.C. § 103(a) - Stabler

Claims 27-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stabler. Applicant respectfully traverses. For the Patent Office to establish *prima facie* obviousness, the Patent Office must show where each and every claim element is taught or suggested in the reference(s). MPEP § 2143.03. Further, the Patent Office is not allowed to extract isolated portions of the reference; rather, the reference must be considered in its entirety. MPEP § 2141.02.

Claims 27-31 depend from independent claim 21. Accordingly, the rejection of claims 27-31 should be withdrawn for at least the same reasons as claim 21 discussed above. Specifically, Stabler provides a target heart rate to the patient to control breathing based on biological feedback from the patient during its instructive method. The claimed invention excludes biological feedback during the entire instructive method. Thus, it is not necessary to address any other points regarding the Patent Office's rejection to overcome this rejection. However, Applicant reserves the right to provide additional arguments against the specific rejections of claims 27-31 in the future, if required.

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant's representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

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